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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,223	01/21/2000	Lori L. Carrigan	P04353US0	5582

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[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1638

DATE MAILED: 01/23/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/489,223	CARRIGAN, LORI L.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 November 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 1-7 and 20 is/are allowed.
- 6) Claim(s) 8-19, 21-42 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objection to the specification for the presence of a blank line on page 7 is withdrawn, in light of the amendment received 13 November 2002.
3. The objection to claims 6, 12, 16, 25, and 29 is withdrawn, in light of the claim amendments.
4. The rejection of claims 1-32 under 35 U.S.C. 112, 2nd paragraph, is withdrawn in light of the claim amendments.
5. The rejection of claims 1-32 under 35 U.S.C. 112, 1st paragraph, requiring a deposit of the maize seed of the invention, is withdrawn in light of the deposit and the deposit statement in the specification and the paper received 13 November 2002.
6. The rejection of claims 1-32 under 35 U.S.C. 102(e)/103(a) is withdrawn in light of the claim amendments.

Claim Rejections - 35 USC § 112

7. Claims 8, 11, 15, 19, 21, 24, 28, 32, 34, and 38-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 8, 21, and 41: the recitation “genetic factor” renders the claims indefinite. It is not clear what is referred to or encompassed by this recitation. It is suggested that the recitation be replaced with --transgene--.

In claims 11, 15, 19, 24, 28, 32: the recitation “significantly different” renders the claims indefinite. It is not clear what makes a trait “significantly different”. The metes and bounds of the claims are not clear.

In claims 11, 15, 19, 24, 28, 32, 38, and 39: the recitations “has derived at least 50% of its alleles” in claims 11, 15, 19, 24, 28, and 32, and “deriving at least 50% of its alleles” in claims 38 and 39 render the claims indefinite. It is not clear what is meant by “derived” and “deriving.” Have the alleles been transformed into the claimed plants, did the claimed plants inherit the alleles in crosses, etc.?

In claim 34: the recitation “essentially” in line 3 renders the claim indefinite. It is not clear what is encompassed by the term. The recitation makes the metes and bounds of the claim unclear.

In claim 38: the recitation “on average, deriving at least 50%” in line 2 renders the claim indefinite. It is not clear what is being referred to by this recitation. The metes and bounds of the claim are not clear.

In claim 39: the recitation “A 38A24 maize plant selected from the population of 38A24 progeny maize plants” renders the claim indefinite. The claim is drawn to plant 38A24, yet can comprise less than 100% of the alleles of 38A24.

In claim 40: the recitation “further comprising applying double haploid methods” renders the claim indefinite. The recitation broadens the scope of parent claim 37, which only involves crosses and does not encompass any double haploid method. It is also not clear what double haploid method is being referred to.

8. Claims 9-19, 22-32 remain and new claims 34-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 13 August 2002 under item 7. Applicant traverses the rejection in the paper received 13 November 2002. Applicant’s arguments have been fully considered but were not found persuasive.

Applicants argue that seed of plant 38A24 has been deposited with the ATCC, and the claims amended to recite the ATCC accession number, and that therefore the written description requirement is met (response, paragraph bridging pages 12-13). However, the rejected claims are not directed towards the deposited seed or the plant that is produced from it. The deposit of seed of plant 38A24 does not provide a description of the plants that are encompassed by the rejected claims, which have not been deposited.

Applicant argues that the claims have been amended by adding the threshold, having 50% of the ancestral alleles, that limits the variation permitted among the genus, as well as an assayable function, capable of expressing a combination of at least two traits of 38A24.

Applicant argues that in plants, identifying characteristics are those detectable in the phenotype, which is manifested through gene expression, and that claims to a particular species of invention are adequately described if the disclosure of relevant identifying characteristics is present in the application. Applicants argue that one of ordinary skill is reasonably apprised in knowing that a plant crossed with 38A24 will result in a plant having half the genetic contribution of 38A24, and that a further limitation set is that the plants must be capable of expressing a combination of at least two phenotypic characteristics of 38A24 (response, paragraph bridging pages 14-15). However, the specification does not provide a description of the alleles of 38A24, nor does it describe the functions that are associated with each of the alleles of 38A24. The specification does not describe the alleles that govern the expression of any of the traits listed in the claims. As the alleles of 38A24 are not described, neither are the alleles of its descendants. Indicating that the claimed plants comprise 50% of the alleles of plant 38A24 does not provide any information concerning the morphological and physiological traits expressed by the plants. That the claimed plants express two traits that are also expressed by 38A24 does not provide any information concerning the remaining traits. Further, the new claims encompass plants that can express any traits, none of which are described. Furtherstill, no description of any trait is provided concerning the other parents of the claimed plants. 50% of the alleles of the claimed plants will also be inherited from the other parent, for which no description is provided.

Applicant also argues that the specification supplies an extensive definition and description of “transgene” and transgenes of interest. Applicant argues that the trivial modification introduced by the transgenes to 38A24 are clearly supported and described in the present application (response, paragraph bridging pages 15-16). However, as written, the claims encompass any and all transgenes, even those that have yet to be isolated and for which descriptions are unknown. Further, the effect that a transgene can have on its host plant depends on the function of its encoded product, among other considerations, and the modification cannot simply be described as “trivial.” A transgene that is a transcription factor, for example, could effect the expression of numerous genes and phenotypes. It is suggested that claims 12 and 25 be amended by listing the types of transgenes that may be introduced, provided that the specification or the prior art indicates that the gene has been isolated, for example transgenes that confer resistance to a plant virus, or which confer male sterility.

Applicants also argue that the claims are definite (response, page 16, 1st paragraph). However, definiteness of the claims is not the issue of this rejection.

Further, the specification does not describe any traits of any inbred plants or any progeny plants produced from 38A24. While plants produced by self or sib pollinating 38A24 would inherit all of their alleles from 38A24, the morphological and physiological characteristics of the progeny plants would be different from those of 38A24, as the genotype of the progeny would not be the same as that of hybrid 38A24. Furtherstill, Applicants mention that they believe that the subject matter of the new claims has literal support in the specification (response, paragraph bridging pages 14-15). However, the specification does not mention any double haploid method.

The amendments to claims 8 and 21 overcome the rejection for those claims.

9. Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim is drawn towards a method of making a hybrid plant designated 38A24 comprising crossing inbred maize plants GE533340 and GE501400.

Claim 33 recites the deposit numbers for two inbred maize plants, and page 7 of the specification indicates that these lines have been deposited with the ATCC. However, the terms of this deposit are not known. If the deposit of these seeds was made under the terms of the Budapest Treaty, then an affidavit or declaration by the Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the deposit was made under the terms of the Budapest Treaty and that the seeds will irrevocably and without restriction or condition be released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

If the deposit was not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and
- (e) the deposit will be replaced if it should ever become inviable.

Summary

10. Claims 1-7 and 20 are allowed. Claims 8-19 and 21-42 are rejected.
11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).
Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

January 20, 2003



ASHWIN D. MEHTA, PH.D
PATENT EXAMINER